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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/854,802	05/14/2001	Bojidar M. Stankov	1259-001	8869

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EXAMINER

CHOI, FRANK I

ART UNIT

PAPER NUMBER

1616

DATE MAILED: 05/30/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Appli ation No.

09/854,802

Applicant(s)

STANKOV, BOJIDAR M.

Examiner

Frank I Choi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION*****Priority***

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Italy on 5/17/2000. It is noted, however, that applicant has not filed a certified copy of the MI2000A 001093 application as required by 35 U.S.C. 119(b).

***Specification***

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

**Arrangement of the Specification**

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

- (a) TITLE OF THE INVENTION.
- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or  
REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (e) BACKGROUND OF THE INVENTION.
  - (1) Field of the Invention.
  - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) BRIEF SUMMARY OF THE INVENTION.
- (g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (h) DETAILED DESCRIPTION OF THE INVENTION.
- (i) CLAIM OR CLAIMS (commencing on a separate sheet).
- (j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino

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acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

This application does not contain an abstract of the disclosure as required by 37

CFR 1.72(b). An abstract on a separate sheet is required.

Further, a section entitled "Brief Description of the Drawing" is also required.

The disclosure is objected to because of the following informalities:

Pg. 1, line 1, "7TITLE" should be "TITLE".

Pg. 1, lines 14-20, the section "description of the invention with the title" appears to be unnecessary and redundant.

Pg. 1 and Pg. 3, there are two sections entitled "SUMMARY". It is suggested that the first section be deleted and set forth as the Abstract.

Pg. 8, line 7, "nucleuss" should be "nucleus".

Pg. 8, line 21, "titanium bioxide" appears to be misspelled.

Claims 1-12 objected to because of the following informalities: Independent claims should begin with a "A" and dependent claims, unless it is the first claim of a different invention, i.e. process dependent on a composition claim, should begin with "The". Further, the format of the claims should preamble, transitional phrase such as "comprising", and body of the claim, for example, "A controlled release formulation comprising melatonin wherein the melatonin, in equal or different doses is contained in both an interior slow release nucleus and exterior fast release cortex", "A process . . .", "The formulation . . .", or "The process for the preparation of controlled release formulations . . .". The use of the phrase "characterized by" or "characterized by the fact" should be avoided, and instead, such terms as "wherein" or "further comprising", etc. should be used.

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Claims 6,7, "nucleuss" should be "nucleus".

Claims 7,9, end in a " ," not a period.

Claim 8 needs a period at the end of the claim.

Appropriate correction is required.

***Claim Rejections - 35 USC § 101/112***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 7, 9, 11-15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites the limitation "active ingredient" and "main ingredient". There is insufficient antecedent basis for these limitation in the claim as melatonin is not defined to be either "active ingredient" or the "main ingredient" in claim 1.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Claim 2 recites the broad recitation "melatonin content" and "may be between 0.1 and 100 mg" which is the narrower statement of the range limitation. Claim 3 recites "contains the active ingredient" and "preferably in a quantity of 1 mg . . . and preferably in a quantity between 0.5 . . . .". Claim 7

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recites “excipients” and “can be calcium phosphate . . . Hydroxypropylmethylcellulose”. Claim 9 contains the limitation that the nucleus is formed from compression of granule from claim 8 and recites “preferable hardness . . .”. Claim 11 recites “preferred excipients” and “may be chosen from hydroxypropyl methyl cellulose . . .”. Because claim 12 is dependent on claim 11 and does not cure the rejection said claim is also rejected. Examiner suggests that the terms or phrases, “can be”, “may be”, “preferred”, “preferably” not be used as they indicate the presence of both broad and narrow ranges or limitations within the claim and imply that the matter following are not required limitations.

Claim 7 lists specified excipients but it is uncertain where said excipients fall into the broader categories of excipients.

Claims 13-15 provides for the use of the formulations according to claim 1, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 13-15 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 149 USPQ 475 (D.D.C. 1966).

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7, 9-12 are rejected under 35 U.S.C. 102(a or b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over, Lee et al. (1999) or Lee et al. (1997), respectively.

The Lee et al. references expressly disclose a dual loaded tablet and process of making the same comprising melatonin in the core and coating falling within the scope of applicant's claims (Lee et al. (1997), abstract; Lee et al. (1999), Pg. 73, 74).

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products and uses that contain the same exact ingredients/components as that of the claimed invention. See In re Fitzgerald, 205 USPQ 594 (CCPA 1980). See also In re May, 197 USPQ 601, 607 (CCPA 1978) and Ex parte Novitski, 26 USPQ2d 1389, 1390-91 (Bd Pat. App. & Inter. 1993).

Claims 1-9 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bromet et al. (US Pat. 5,879,710).

Bromet et al. expressly disclose a dual loaded tablet and process of making the same comprising melatonin in the core and coating falling within the scope of applicant's claims (Column 6, lines 46-68, Column 7).

Alternatively, at the very least the claimed invention is rendered obvious within the meaning of 35 USC 103, because the prior art discloses products and uses that contain the same exact ingredients/components as that of the claimed invention. See *In re Fitzgerald*, 205 USPQ 594 (CCPA 1980). See also *In re May*, 197 USPQ 601, 607 (CCPA 1978) and *Ex parte Novitski*, 26 USPQ2d 1389, 1390-91 (Bd Pat. App. & Inter. 1993).

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (1999) or Lee et al. (1997) in view of Bromet (US Pat. 5,879,710) or Flaugh (US Pat. 5,654,325).

Lee et al. (1999) or Lee et al. (1997) disclose a dual loaded tablet and process of making the same comprising melatonin in the core and coating (Lee et al. (1997), abstract; Lee et al. (1999), Pg. 73, 74).

Bromet or Flaugh teach melatonin containing dosage forms which are prepared by granulation and compression of said granules (Bromet, Column 6, lines 46-68, Column 7; Flaugh, Column 8, lines 25-48, Column 9, lines 64-68, Column 10, lines 1-25).

The difference between the prior art and the claimed invention is that the Lee et al. references do not expressly disclose a process wherein the nucleus of the controlled release formulation is prepared by granulation, calibration of the granulation and controlled pressure compression. However, the prior art amply suggests the same as it is known in the art to prepare tablets by preparation and compression of granules. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as



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above with the expectation that release of melatonin could be modified as desired depending on the formulation of the dosage form.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

### *Conclusion*

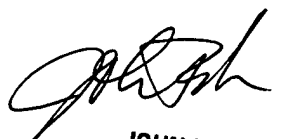
A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machines are (703) 308-4556 or (703) 305-3592.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (703) 308-0067. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. José Dees, can be reached on (703) 308-4628. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (703) 308-1235 and (703) 308-0198, respectively.

FIC

May 23, 2002

  
JOHN PAK  
PRIMARY EXAMINER  
GROUP 1200

